

## REMARKS

### Status of the Claims

Claims 1-2, 7-15 and 20-22 are pending, of which claims 8-14 and 20-22 are withdrawn from consideration. Claims 1-2, 7, and 15 stand rejected. Claim 23 is newly added. Support for claim 23 may be found in the application as filed. Accordingly, no new matter has been added.

### Rejections

Claims 1-2, 7, and 15 are rejected under 35 U.S.C. § 102 as allegedly anticipated by U.S. Patent No. 6,544,564 (“Farley”) or U.S. Patent Publication No. 2002/0115708 (“Safe”). In particular, it is alleged that “[a] subject predisposed to an androgen-dependent pathology could virtually be anyone” and “[b]ased on [Farley teaching DIM and formulas to treat an androgen-insensitive PC-3 cell line], the inherency is evident with regard to a treatment of cancer.” *OA dated February 24, 2010*, at pp. 3-4. It is also alleged that Safe “teach that the DIM series of compounds . . . can be used for treating multiple cancers [including] two additional androgen-responsive prostate cancer cell lines” and that “it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to consider the teachings of Safe et al. in obviousness over the claimed invention.” *Id.*, at p. 5, 7.<sup>1</sup>

Applicants respectfully disagree. First, Applicants note that the claims are not directed toward providing the claimed antiandrogen to “virtually anyone”, but rather, toward hosts that are subject or predisposed to a pathology selected from the group consisting of prostate hyperplasia, acne, androgenetic alopecia and hirsutism. Second, neither Farley nor Safe teach or suggest providing their disclosed compounds to hosts subject or predisposed to such pathologies. Third, the teachings related to prostate cancer by both Farley and Safe are inapposite to the patentability of the present claims.

Claim 1 was amended in a previous submission to recite “wherein the host is a human patient determined to be subject or predisposed to an androgen-dependent pathology selected from the group consisting of prostate hyperplasia, acne, androgenetic alopecia and hirsutism” (emphasis added). Applicants respectfully assert that since this clause relates back to and

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<sup>1</sup> It is unclear whether the rejection based on Farley is under 35 U.S.C. 102 or 35 U.S.C. 103. However, the arguments provided below are relevant to both scenarios since Farley does not teach OR suggest providing an antiandrogen to a host subject or predisposed to prostate hyperplasia, acne, androgenetic alopecia, or hirsutism.

clarifies what is required by the claim, it should be given a limiting effect. *See, e.g.*, M.P.E.P. § 2111.04 (stating “when a ‘whereby’ clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention”); *see also Griffin v. Bertina* 285 F.3d 1029, 1033-34 (holding that the wherein clause at issue must be given limiting effect because it relates back to and clarifies what is required by the claim.)). Accordingly, Applicants respectfully assert that it is contrary to established patent law to allege that the claims are directed toward providing the subject antiandrogen to “virtually anyone.” In fact, the claims are directed toward providing the subject antiandrogen to a host determined to be subject or predisposed to prostate hyperplasia, acne, androgenetic alopecia or hirsutism

Anticipation requires that each and every limitation of the claims be disclosed, either expressly or inherently, in a single prior art reference. *See, e.g.*, MPEP § 2131. The Office has failed to show that either Farley or Safe teach providing the claimed antiandrogen to a host subject to or predisposed to a pathology selected from the group consisting of prostate hyperplasia, acne, androgenetic alopecia or hirsutism. Instead, it is emphasized that both references teach use of the compound(s) respectively disclosed therein against prostate cancer cell lines. Applicants fail to see how this teaching is relevant to the present claims since none of the recited pathologies are cancerous. Applicants note for the record that although some of the symptoms of prostate hyperplasia and prostate cancer are the same, there is no apparent relation between the two pathologies. *See, e.g.*, Guess (2001) *Epidemiologic Reviews* 23:154-58, at p. 155 last full paragraph (stating “On the basis of available biologic evidence, benign prostatic hyperplasia appears to be etiologically unrelated to prostatic adenocarcinomas.”). Further Applicants can find no explicit teaching in either Farley or Safe regarding hosts subject predisposed to prostate hyperplasia, acne, androgenetic alopecia or hirsutism. Accordingly, neither Farley nor Safe anticipate the present claims.

It is stated that “the inherency is evident with regard to a treatment of cancer” with regard to Farley. *OA dated February 24, 2010*, at p. 4. Applicants reiterate that the treatment of cancer is irrelevant for this case. Applicants further submit that this case is controlled by the inherency framework explained by the Court of Appeals for the Federal Circuit in *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). In that case, the Court held that the prior art did not invalidate claims directed toward application of a composition to sunburned skin since the prior art only disclosed application of the composition to skin in general, not sunburned skin in

particular. *Id.*, at p. 1379. Here, there is no rationale or proof that the hosts disclosed by Safe or Farley are subject or predisposed to prostate hyperplasia, acne, androgenetic alopecia, or hirsutism. Accordingly, neither Safe or Farley expressly or inherently teach or suggest providing the claimed antiandrogen to such hosts.

For the sake of completeness, Applicants also submit that the claims are not obvious over any of the cited references for at least the reason that every limitation of the claims is not taught or suggested by any permissible combination of the references. In particular, it is reiterated that none teach or suggest providing an antiandrogen to a host subject or predisposed to prostate hyperplasia, acne, androgenetic alopecia, or hirsutism.

Claim 23 is identical to claim 1 with the exception that the recitation of “predisposed” has been deleted. Claim 23 is added without (1) acquiescing to the allegation that claims 1-2, 7, and 15 are directed toward “[a] subject predisposed to an androgen-dependent pathology [and thus] . . . virtually . . . anyone.” and (2) solely for the purpose of expediting prosecution. *See, OA dated February 24, 2010*, at p. 3. Since the method of claim 23 is encompassed by the method of claim 1, new claim 23 will not require the Examiner perform any new search. Accordingly, Applicants respectfully request its entry. Additionally, Applicants respectfully assert that claim 23 is also patentable over Farley and Safe for the reasons stated above.

Having distinguished the independent claims from the art of record, Applicants submit that the claims dependent therefrom are patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of those claims in the future, should that be necessary.


### **CONCLUSION**

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the above amendment and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned by telephone at (415) 356-3064 or by fax at (415) 356-3099.

No fees are believed due, however the Commissioner is hereby authorized to charge any fees associated with this communication, and/or credit any overpayment to Deposit Account No. 50-2387.

Respectfully submitted,  
ARNOLD & PORTER LLP

Dated: 6/24/10  
**Customer Number: 28381**  
Arnold & Porter LLP  
275 Battery Street, Suite 2700  
San Francisco, CA 94111  
Telephone: (415) 356-3000  
Facsimile: (415) 356-3099

By:   
Todd A. Lorenz, Reg. No. 39,754

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